

TERUMO CORPORATION
SURFLASH® Safety I.V. Catheter
Section 5. 510(k) Summary

MAY 30 2014

510(k) SUMMARY**A. SUBMITTER INFORMATION (807.92(a)(1))**

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Prepared for: *Owner/Operator*
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Date prepared: May 1, 2014

B. DEVICE NAME (807.92(a)(2))

Proprietary Name: SURFLASH® Safety I.V. Catheter
Common Name: Intravascular Catheter
Classification Name: Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
Regulation Number: 21 CFR 880.5200
Regulatory Class: II
Review Panel: General Hospital
Product Code: FOZ

C. PREDICATE DEVICE (807.92(a)(3))

The legally marketed device to which substantial equivalence is claimed is the current device, SURFLASH® Safety I.V. Catheter (K122544), manufactured by Kofu Factory of Terumo Corporation.

D. REASON FOR 510(K) SUBMISSION

This Special 510(k) is being submitted due to a design modification to the previously cleared device to extend the range of product offering to include 14G and 16G catheters and a new length of 51 mm (2”).

E. DEVICE DESCRIPTION (807.92(a)(4))

(SUMMARY OF TECHNOLOGICAL CHARACTERISTICS)

Principle of Operation/Technology

The SURFLASH® Safety I.V. Catheter is manually operated and contains a passive safety feature that automatically activates as the needle is withdrawn from the catheter.

Design/Construction

The SURFLASH® Safety I.V. Catheter is a device consisting of catheter assembly (catheter, caulking pin, and catheter hub), needle assembly (needle, needle housing, transparent flash chamber (needle connecting part) with filter, and needle protector) and a passive needle-shielding mechanism (shutter and needle shaft cover consisting of inner cylinder, outer cylinder, and junction cylinder).

The devices are an over-the needle, peripheral catheter made of a slender, flexible,

radio-opaque plastic with a hub that is inserted into the patient's vascular system for short term (<30 days) use to withdraw blood samples, administer fluids intravenously, or monitor blood pressure by attaching a monitoring line.

The grooved cannula, which allows the clinician to visualize flashback detection through the groove, indicates that there is confirmation of vessel entry. The whole length of the cannula, including the sharp end of the cannula, is covered by the needle shielding mechanism as the needle is withdrawn from catheter's hub to aid in the prevention of needle stick injuries.

Material

The stainless steel cannula is placed in the catheter to maintain rigidity and is withdrawn after the catheter is placed in the vascular system. The catheter that is advanced into the vessel is made of polyurethane.

Specifications

The modified SURFLASH® Safety I.V. Catheter is available in 3 sizes, with combinations of 14 and 16 gauge catheter diameters and 32 and 51 mm (1 ¼" and 2") lengths.

F. INTENDED USE (807.92(a)(5))

The SURFLASH® Safety I.V. Catheter is inserted into the patient's vascular system for short term use (<30 days) to withdraw blood samples, administer fluid intravenously, or monitor blood pressure by attaching a monitoring line. The needle shaft cover and tip shield feature aids in the prevention of needle stick injuries. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy. The 18 to 22 gauge catheters are suitable for use with power injectors rated for a maximum of 325 psi.

Note: This intended use is identical to the predicate device, K122544.

G. TECHNOLOGICAL CHARACTERISTIC COMPARISON (807.92(a)(6))

The SURFLASH® Safety I.V. Catheter, subject of this Special 510(k), has the same technological characteristics as the SURFLASH® Safety I.V. Catheter (K122544) in

terms of operation principle, design/construction, material and specifications.

A comparison of the technological characteristics is summarized on the table below.

Comparison of the technological characteristics to predicate device		
Trade Name	Modified SURFLASH® Safety I.V. Catheter (subject of this 510(k))	Current SURFLASH® Safety I.V. Catheter (K122544)
Manufacturer	Terumo Corporation	Terumo Corporation
Operation principle	Conduit as fluid pathway. Operated manually. Identical to the current K122544	Conduit as fluid pathway. Operated manually.
Design / Construction	a. Catheter assembly (Catheter*, caulking pin* and catheter hub*) b. Needle assembly (Needle*, Needle housing and Transparent flash chamber (needle connecting part)) c. Needle shield assembly (Shutter, Inner cylinder, Outer cylinder, Junction cylinder) d. Filter (Filter cap not available) e. Needle protector * Contacting patient body directly or indirectly Identical to the current K122544	a. Catheter assembly (Catheter*, caulking pin* and catheter hub*) b. Needle assembly (Needle*, Needle housing and Transparent flash chamber (needle connecting part)) c. Needle shield assembly (Shutter, Inner cylinder, Outer cylinder, Junction cylinder) d. Filter (Filter cap not available) e. Needle protector * Contacting patient body directly or indirectly
Needle Shape / Material	Notched cannula. Ditch on the cannula surface from the heel of the bevel to rear of the catheter tip. Stainless steel Identical to the current K122544	Notched cannula. Ditch on the cannula surface from the heel of the bevel to rear of the catheter tip. Stainless steel
Flashback	When catheter and needle are properly placed inside vessel, flashback can be confirmed after blood flows through ditch on the cannula surface. Identical to the current K122544	When catheter and needle are properly placed inside vessel, flashback can be confirmed after blood flows through ditch on the cannula surface.
Catheter material	Polyurethane Biocompatibility of material confirmed. Identical to the current K122544	Polyurethane Biocompatibility of material confirmed.
Radiopaque medium	Yes (Barium sulfate) Identical to the current K122544	Yes (Barium sulfate)

Comparison of the technological characteristics to predicate device		
Trade Name	Modified SURFLASH® Safety I.V. Catheter (subject of this 510(k))	Current SURFLASH® Safety I.V. Catheter (K122544)
Safety mechanism	<ul style="list-style-type: none"> * Passive needle shielding * A needle shield passively covers the inner needle when the needle is withdrawn from the catheter. * Whole length cannula including cannula tip is shielded. <p>Identical to the current K122544</p>	<ul style="list-style-type: none"> * Passive needle shielding * A needle shield passively covers the inner needle when the needle is withdrawn from the catheter. * Whole length cannula including cannula tip is shielded.
Color code of catheter hub	<p>In accordance with ISO 10555-5</p> <p>Identical to the current K122544</p>	In accordance with ISO 10555-5
Package	<p>Sterility barrier: Blister package, Cast Polypropylene(CPP) /Polyethylene(PE) two layer laminated film and paper Unit box Cardboard</p> <p>Identical to the current K122544</p>	<p>Sterility barrier: Blister package Cast Polypropylene(CPP) /Polyethylene(PE) two layer laminated film and paper Unit box Cardboard</p>
Sterilization method	<p>Ethylene oxide</p> <p>Identical to the current K1225400</p>	Ethylene oxide
Range of Sizes	14 and 16G, 1 ¼" – 2"	18-24G, ¾" – 1 ¼"

H. NON CLINICAL TESTS (807.92(b)(1))

Performance

Performance testing was conducted to ensure the safety and effectiveness of the SURFLASH® Safety I.V. Catheter throughout the shelf life, verify conformity to the applicable part of ISO standards, and demonstrate substantial equivalence to the predicate device. Additionally, performance testing other than to the ISO Standards was performed on the device to verify the modified device against the current. The device complies with the acceptance criteria established based on the predicate.

No new issues of safety and effectiveness were raised with the testing performed. Performance testing demonstrates that the SURFLASH® Safety I.V. Catheter conforms to the ISO standards, is substantially equivalent to the predicate device, and is acceptable for clinical use throughout the shelf life.

The following performance tests were performed on the device:

TERUMO CORPORATION
SURFLASH® Safety I.V. Catheter
Section 5. 510(k) Summary

Performance test	Testing			
	Compliance to ISO			Testing by internal standard
	ISO 23908	ISO 10555-1	ISO 10555-5	
Force to needle breaking shutter (Puncture resistance of needle shield)	X	Not required	Not required	Required by ISO
Tensile strength of needle shaft and needle housing (Break strength of safety mechanism)	X	Not required	Not required	Required by ISO
Force to release shutter and reactive force when the shutter opens to cover the cannula tip (Reaction force generated by the activation mechanism)	Not required	Not required	Not required	X
Force to detach needle shaft cover from catheter hub (Force to activate safety feature)	X	Not required	Not required	Required by ISO
Simulated maximum pressure	Not required	Not required	Not required	X
Burst pressure (whole device)	Not required	X	Not required	Required by ISO
Collapse (under negative pressure)	Not required	X	Not required	Required by ISO
Catheter to catheter hub tensile strength (Force at break of catheter / hub)	Not required	X	Not required	Required by ISO
Strength of union between transparent flash chamber (needle connecting part) and needle	Not required	Not required	X	Required by ISO
Needle attachment to catheter (Initial sliding friction)	Not required	Not required	Not required	X
Detection of flashback at catheter tip	Not required	Not required	Not required	X
Detection of flashback at transparent flash chamber (needle connecting part)	Not required	Not required	X	Required by ISO
Flow rate	Not required	Not required	X	Required by ISO
Vent fitting	Not required	Not required	X	Required by ISO
Drop test	Not required	Not required	Not required	X
Conical fittings of catheter hub	Not required	X	Not required	Required by ISO
Pressure monitoring	Not required	Not required	Not required	X
Simulated use study	X	Not required	Not required	Required by ISO
Surface	Not required	X	Not required	Required by ISO
Corrosion resistance	Not required	X	Not required	Required by ISO
Radio-detectability	Not required	Not required	X	Required by ISO
Catheter unit	Not required	Not required	X	Required by ISO
Material	Not required	Not required	X	Required by ISO
Needle point	Not required	Not required	X	Required by ISO
Catheter body tensile strength (Force at break)	Not required	X	Not required	Required by ISO
Catheter Stiffness	Not required	Not required	Not required	X
Catheter Elongation	Not required	Not required	Not required	X
Catheter Flexural fatigue tolerance	Not required	Not required	Not required	X

X: Confirmed the conformance to the standard.

No deviations from ISO standards were identified in the testing to standards.

Simulated Use Study

An additional simulated use study was conducted in accordance with FDA's Guidance for Industry and Staff, Medical Devices with Sharps Injury Prevention Features, issued on August 9, 2005 and ISO 23908: 2011, *Sharps injury protection—Requirements and test methods—Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*. The objectives of this study were designed to confirm that study participants are able to read and follow the Instructions for Use to safely and effectively operate the safety feature of the modified device. The objectives were:

1. Verify that proper activation of the sharps injury prevention feature of the device can be accomplished in simulated clinical environments by healthcare workers who use these types of Safety I.V. Catheters.
2. Determine if the Instructions for Use are adequate for proper activation of the sharps injury prevention feature.

All safety features activated effectively and there were no de-activations after discarding. All participants were able to read and activate the catheter safety feature without further explanation or training.

Conclusion: The safety feature of the device operates safely and effectively as intended. Users with various levels of experience can read the IFU and operate the device safely and effectively.

Biocompatibility

In accordance with ISO 10993-1, the SURFLASH® Safety I.V. Catheter is classified as:

- Catheter and lubricant: Externally Communicating Device, Circulating Blood, Prolonged Exposure (24 hours to 30 days).
- All other materials contacting with patient's body: Externally Communicating Device, Blood Path Indirect, Prolonged Exposure (24 hours to 30 days).

As mentioned in the below table, the device's materials contacting with the patient's

body were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO – 10993, *Biological Evaluation of Medical Devices part 1: Evaluation and Testing*.

Screening tests were performed on accelerated aged whole devices to show that the biocompatibility is maintained throughout the shelf life of the product. Results of the testing demonstrate that the materials contacting with patient's body are biocompatible throughout the shelf life of the product.

Test
Cytotoxicity
Sensitization
Intracutaneous reactivity
Systemic toxicity (acute)
Pyrogen
Genotoxicity
Implantation / Subchronic toxicity
Hemolysis
Physicochemical
Characterization

Biocompatibility of the device and materials was established under K122544 for the current SURFLASH® Safety I.V. Catheter, manufactured by Kofu Factory of Terumo Corporation. None of the data raises any new issues of safety and effectiveness.

No changes have been made since 510(k) clearance that would require re-testing; therefore, biocompatibility established under K122544 is still applicable.

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with Method C: Half-cycle method in Annex B of EN ISO11135-1: 2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. The SURFLASH® Safety I.V. Catheter is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6} .

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971: 2007, taking into account the modifications to the previous device, and it was determined that there were no new issues of safety or effectiveness.

I. CLINICAL TESTS (807.92(b)(2))

This 510(k) does not include data from clinical tests.

J. CONCLUSION (807.92(b)(3))

In summary, the SURFLASH® Safety I.V. Catheter, subject of this Special 510(k), is substantially equivalent in its intended use, technology / principal of operation, materials, and performance to the current device:

SURFLASH® Safety I.V. Catheter (K122544), manufactured by Kofu Factory of Terumo Corporation, Japan.

There is no significant difference that raises any new issues of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

May 30, 2014

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Terumo Medical Corporation
Mr. Phillip Lester
Regulatory Affairs Specialist
950 Elkton Boulevard
Elkton, MD 21921

Re: K141138
Trade/Device Name: SURFLASH® Safety I.V. Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: May 1, 2014
Received: May 2, 2014

Dear Mr. Lester:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mary  Bunner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141138

Device Name

SURFLASH® Safety I.V. Catheter

Indications for Use (Describe)

The SURFLASH® Safety I.V. Catheter is inserted into the patient's vascular system for short term use (<30 days) to withdraw blood samples, administer fluid intravenously, or monitor blood pressure by attaching a monitoring line. The needle shaft cover and tip shield feature aids in the prevention of needle stick injuries. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy. The 18 to 22 gauge catheters are suitable for use with power injectors rated for a maximum of 325 psi.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



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Richard C. Chapman -5
Date: 2014.05.30
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